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09/891,983	06/26/2001	Dinesh O. Shah	6821.US.01	9651

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/891,983	SHAH ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,9,13,14,18-21 and 23-25* is/are pending in the application.

4a) Of the above claim(s) *18-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,9,13,14 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Currently, claims 1-6, 8, 9, 13, 14, 18-21, and 23-25 are pending in the application. Claims 18-21 are withdrawn as to non-elected inventions. In the prior action, mailed on October 17, 2003, claims 1-11, and 13-15 were rejected, and claims 18-21 stood withdrawn as to non-elected inventions. In the Amendment filed on May 24, 2004, the Applicant amended claims 4, 8, and 13; cancelled claims 7, 10, 11, and 15; and added new claims 23-25.

Claim Objections

2. **(New Objection-Necessitated by Amendment)** Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. This claim depends from claim 23, which describes a kit comprising an antibody coated onto a solid phase, wherein said antibody is C11-14. Claim 25 attempts to limit the invention of claim 23 to embodiments "wherein said antibody is C11-10." Claim 25 therefore appears to be attempting to change, rather than to further limit, the invention of claim 23. The claim is therefore not properly dependant on claim 23. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **(New Rejection-Necessitated by Amendment)** Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 is treated as representative. This claim has been amended to read on a method comprising the step of contacting a test sample with "2) at least one HCV antibody or portion thereof coated on said solid phase, for a time and under conditions sufficient for the formation of antigen/antibody complexes, wherein said at least one antibody coated on said solid phase is C11-14." The claim both indicates that the composition coating the solid phase may be either an "HCV antibody" or a "portion thereof." However, the claim also indicates that the antibody is antibody C11-14. It is not clear if the claim is intended to cover embodiments comprising only the whole antibody C11-14, or if the claims are also intended to cover embodiments wherein the solid phase is coated only with the antigen-binding portion of that antibody. Clarification is required.

5. **(New Rejection-Necessitated by Amendment)** Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim reads on the kit of claim 23 "wherein said antibody is C11-10." However, claim 23 describes a kit "wherein said one HCV antibody is C11-14." Thus, claim 14 specifically identifies the antibody as an antibody other than that of C11-10. Claim 25 therefore appears to change, rather than to further limit, the invention of claim 23. Because the limitations of claim 25 are not consistent with those of claim 23, it is unclear what is being claimed. Clarification is required.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **(Prior Rejection- Withdrawn)** Claims 3 and 10 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claim 10 has been cancelled from the application. The rejection is therefore withdrawn from this claim. Claim 3 was rejected for lack of written description regarding the methods using the monoclonal antibodies 107-35-54 and 110-81-17. The Applicant has submitted a Declaration under 37 CFR 1.132 by Scott Muerhoff indicating that these two antibodies are identical to the monoclonal antibodies refereed to as H35C54 and H81C17 described and claimed in U.S. Patent 5,753,430. In view of this, and the fact that the patent and declaration indicate that such antibodies were publicly available and known to those in the art at the time of filing of the instant application, the rejection is withdrawn.

8. **(New Rejection-Necessitated by Amendment)** Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 8 has been amended to read on embodiments of the claimed invention wherein the antibody bound to the solid phase for the detection of HCV core antigen is antibody C11-14, and such that the second antibody used to detect the anti-HCV serum antibody

is antibody C11-10. However, antibody C11-10 is disclosed in the application as specifically binding to the HCV core antigen, and not to the anti-HCV antibody being detected by the HCV antigen coated on a solid phase. Because the C11-10 antibody is not disclosed as capable of binding to the detected antibody, and because there is no evidence that the C11-10 antibody would be capable of detecting the bound anti-HCV antibody, the Applicant is not enabled for methods of using the C11-10 antibody to detect the bound anti-HCV antibody.

From the Applicant's arguments, and the teachings in the specification, it appears that the applicant intended to amend the claims such that C11-10 antibody would be used to detect the HCV antigen bound by the C11-14 antibody coated on a solid phase (i.e. to be used as the third antibody used to detect the antigen bound in subpart (a)(2) of the claim, rather than as the second antibody used to detect the complex formed in subpart (a)(1) of the claim).

9. **(New Rejection-Necessitated by Amendment)** Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection. The claims, as amended, have been described above. As was indicated above, the application does not provide any disclosure regarding the use of the C11-10 antibody to detect anti-HCV antibody bound to the antigen coated on a solid phase in subpart (a)(1) of the claimed method. Thus, the amended claim appears to have added new matter to the application. The Applicant is

requested to point out where in the application support may be found for the claimed subject matter, or to cancel the New Matter from the application.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. **(Prior Rejection- Maintained in part)** Claims 1-6 were rejected under 35 U.S.C. 102(b) as being anticipated by Aoyagi et al. (WO 00/07023, the English language translation of is found as U.S. Patent 6,623,921). The claim read on methods for the simultaneous detection of an HCV antigen and an HCV antibody. Such methods are taught by Aoyagi. It was noted in the prior action that the reference further teaches the use of antibodies C11-14, C11-10, C11-3, and C11-7. The Applicant has amended claim 3 such that this claim no longer recites the indicated antibodies. The rejection is therefore withdrawn from claims 3 and 4. However, claims 1, 2, 5, and 6 do not exclude the use of the indicated antibodies. These claims are generic to the invention of claim 3, and therefore the amendment of claim 3 has not affected the scope of these claims, or the applicability of Aoyagi against them. The rejection is therefore maintained against claims 1, 2, 5, and 6.

12. **(Prior Rejections- Withdrawn)** Claims 1, 2, 4, 13, and 14 were rejected under 35 U.S.C. 102(e) as being anticipated by Chien et al., (U.S. Pub 2002/0192639), and claims 1, 2, 4-6, 13, and 14 were rejected under 35 U.S.C. 102(e) as being anticipated by Bahl et al., (U.S. Pub 2003/0049608). The Applicant submitted a Declaration under 37 CFR 1.131 with the Response filed on January 15 (and May 24) 2004 to demonstrate possession of the claimed inventions prior to the earliest filing dates of the Chien and Bahl references. The Declaration under 37 CFR 1.131 is sufficient to overcome the rejection over these references. The rejections are therefore withdrawn.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. **(Prior Rejection- Reformed as necessitated by amendment and Maintained)** Claims 13 and 14 were rejected under 35 U.S.C. 102(e) as anticipated by, or in the alternative, under 35 U.S.C. 103(a) as being unpatentable over Aoyagi (WO 00/07023- as translated in U.S. Patent 6,623,921). Claim 13 has been amended to require that the kit comprises one of a list of specific antibodies. The Applicant argues that the Aoyagi reference does not teach kits comprising such antibodies, and that the reference does not, therefore, render the claimed inventions obvious.

This argument is found persuasive. The rejection is therefore reformed such that claims 3, 4, 13, and 14 are now rejected over the teachings of Aoyagi in view of Mehta et al. (US Patent 5,753,430- of record in the IDS filed on January 28, 2002).

The Aoyagi reference has been described above, and in the prior actions. While the reference does not identify the antibodies identified in claims 3 or 13, the reference relates to the use of anti-Core antibodies in general. See e.g. column 1, lines 10-15). It would therefore have been obvious to those in the art to use antibodies known in the art other than those disclosed by the reference.

The Applicant has indicated, in the Declaration of Scott Muerhoff, that the antibodies referred to in the claims as 107-35-54 and 110-87-17 were disclosed by the Mehta patent. See, Declaration, page 2; and Mehta, col. column 2 lines 45-55, and claim 1. These antibodies are disclosed as antibodies that bind to the HCV core protein. Claim 1. Because this reference teaches that these antibodies may be used in the detection of HCV (see e.g., claim 10), and because Aoyagi teaches that such antibodies may be used in the method disclosed therein, it would have been obvious to those in the art to use these antibodies in the methods described by Aoyagi. It would therefore also have been obvious to those in the art to have constructed the claimed kits for use in the described methods. The reformed rejection is therefore maintained against claims 13 and 14, and extended to amended claims 3 and 4.

15. **(Prior Rejection- Withdrawn)** Claims 7, 8-11, and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/07023. Claims 7, 10, 11, and 15 have been cancelled from the application. The rejection is therefore withdrawn from these claims. Claims 8 and 9

have been amended such that the antibody coated on the solid phase is antibody C11-14, and the antibody used to detect the bound anti-NCV antibody is the C11-10 antibody. Such a use of the C11-10 antibody is not disclosed by the art. The rejection is therefore withdrawn.

However, it is also noted that the Applicant appears to have intended that the c11-10 antibody would be used to detect the HCV core antigen that complexes with the c11-14 antibody coated on a solid phase. Response, pages 9-10. The Applicant argues that this combination of antibodies for the detection of HCV core antigen is non-obvious over the prior art as providing unexpected results over the prior art. Id. If the claims were so amended such that the embodiment that the Applicant intended to claim was actually described in the claims, this argument would be found persuasive. Claims reading on the inventions as argued by the Applicant (i.e. inventions wherein the C11-14 antibody is coating the solid phase, and using the C11-10 antibody to detect antigen bound to the C11-14 antibody) would appear to be allowable over the prior art.

16. **(Prior Rejections- Withdrawn)** Claims 7-11, and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chien, and claims 8-12, 14, and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bahl in view of Chien. As was indicated above, the Applicant has submitted evidence in the form of a Declaration under 35 CFR 1.131 that Applicant was in possession of the claimed inventions prior to the earliest priority date of either the Chien or Bahl references. The rejections over these references are therefore withdrawn.

17. **(New Rejection-Necessitated by Amendment)** Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyagi as applied to claims 13 and 14 in the prior action. These claims have been described above. For the purposes of this rejection, claim 25 is interpreted as describing a kit comprising the a solid phase coated with the C11-10 antibody instead of the C11-14 antibody. As was noted with respect to claims 1-6 in the prior action, Aoyagi teaches the use of antibodies C11-10 and C11-14 in methods to simultaneously detect HCV antigens and antibodies in a sample. It would therefore have been obvious to those in the art to make kits such as those described in claims 23-25.

Conclusion

18. No claims are allowed.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

James C. Housel 7/12/04

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